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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,423	10/12/2001	Kirk Hogan	HOGAN-06650	2436

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 01/21/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,423

Applicant(s)

HOGAN, KIRK

Examiner

Jeanine A Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed January 8, 2003. Currently, claims 24-44 are pending.

Election/Restrictions

2. Applicant's election without traverse of Group II in Paper No. 6 is acknowledged.

Priority

3. This application claims priority as a continuation in part of 09/613,887, filed July 11, 2000.

Drawings

4. The drawings are approved by the examiner.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 24-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 24-44 recite "reagents capable of detecting the presence of variant alleles of two or more genes selected from the group consisting of...." This recitation is indefinite because it is unclear whether the reagents in fact detect the presence of variant alleles of two or more genes. Moreover, it is unclear what constitutes a reagent

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capable of detecting the presence of variant alleles. It is unclear whether the reagent must be used to differentiate alleles of two or more genes, whether the reagent must be any reagent in any chemical assay used.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 24-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim 1997 Biochemicals Catalog (page 95, Nucleic Acid Labeling and Detection).

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, with regard to the limitation that the kits contain instructions for using said kit for generating said perioperative genomic profile for said subject, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit.

Boehringer Mannheim provides several products which are packaged for distribution, kits, which allow for detecting the presence of variant alleles of two or more genes. First, Boehringer Mannheim teaches Digoxigenin-3-O-methylcarbonyl-e-aminocaproic acid-N-hydroxy-succinimide ester which is suitable for 5'-end labeling of oligonucleotides. The label is thus capable of detecting the presence of variant alleles in hybridization assays using ASO probes, for example. Second, Boehringer Mannheim teaches hybridization bags which can be used in non-radioactive hybridization and detection procedures, standard radioactive probe hybridizations and Western blotting procedures. Third, Boehringer Mannheim teaches lumi-Film Chemiluminescent Detection film which is "ideal for detecting the signals from alkaline phosphatase chemiluminescent substrates in membrane hybridization techniques." These three products are only examples of a few of the products distributed by Boehringer Mannheim which are "capable of detecting the presence of variant alleles of two or more genes."

The claims also require "instructions for using said kit for generating said perioperative genomic profile for said subject." Because no patentable weight is given to the written material in the instructions describing a method, the claim is anticipated by Boehringer Mannheim Catalog. In the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." The instructions of the instant kit are not considered to distinguish the claimed kits over the prior art. Moreover, *In re Haller* states that, in accordance with the

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patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. *If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it was intended.* The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Therefore, since Boehringer Mannheim teaches every limitation of the claims, Boehringer Mannheim anticipates the claimed invention.

7. Claims 24-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Perkin Elmer, PCR Systems, Reagents & Consumables (1995-1996, pages 15-18).

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, with regard to the limitation that the kits contain instructions for using said kit for generating said perioperative genomic profile for said subject, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit.

Perkin Elmer provides several products which are packaged for distribution, kits, which allow for detecting the presence of variant alleles of two or more genes. First,

Perkin Elmer teaches the GeneAmp PCR Reagent Kit with AmpliTaq DNA polymerase. The kit contains the components of AmpliTaq DNA polymerase, GeneAmp Buffer, GeneAmp dNTPs, GeneAmp Lambda Control Reagents and package insert with PCR protocols (page 15). This kit provided by Perkin Elmer contains reagents which allow for detection of variant alleles of two or more genes. Perskin Elmer provides several additional variations of the PCR kit (page 16-18).

The claims also require "instructions for using said kit for generating said perioperative genomic profile for said subject." Because no patentable weight is given to the written material in the instructions describing a method, the claim is anticipated by Boehringer Mannheim Catalog. In the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." The instructions of the instant kit are not considered to distinguish the claimed kits over the prior art. Moreover, *In re Haller* states that, in accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. *If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it was intended.* The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Therefore, since Perkin Elmer teaches every limitation of the claims, Perkin Elmer anticipates the claimed invention.

8. Claims 24-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Applied Biosystems Product Catalog (1993, pages 135-164).

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, with regard to the limitation that the kits contain instructions for using said kit for generating said perioperative genomic profile for said subject, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit.

Applied Biosystems provides several products which are packaged for distribution, kits, which allow for detecting the presence of variant alleles of two or more genes. Applied Biosystems products for sale include: a DNA analysis system; software for genetic analysis; electrophoresis accessories including combs, alignment braces, glass plates, manuals; PRISM Ready reaction cycle sequencing kits; AmpliTaq Cycling Sequencing Kits; DNA sequencing Neat reagents Dye primers; activated dyes, template purification kits; etc. Each of these products is capable of detecting the presence of variant alleles of two or more genes.

The claims also require "instructions for using said kit for generating said perioperative genomic profile for said subject." Because no patentable weight is given to the written material in the instructions describing a method, the claim is anticipated by Boehringer Mannheim Catalog. In the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." The instructions of the instant kit are not considered to distinguish the claimed kits over the prior art. Moreover, *In re Haller* states that, in accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. *If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it was intended.* The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Therefore, since Applied Biosystems teaches every limitation of the claims, Applied Biosystems anticipates the claimed invention.

Conclusion


9. No claims allowable over the art.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Jeanine Goldberg
January 14, 2003


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600